K063157

MAR 10 2008

Merries International Inc.
2F 3-1, Bau-Hung Rd.,
Shin-Tien Taipei, Taiwan,

510(k) PREMARKET NOTIFICATION
SUMMARY OF SAFETY AND EFFECTIVENESS

In accordance with the requirements of 21CFR 807.92

Merries K-PHATE *Bone graft substitute*

1. Submitted by:
   Merries International Inc.
   2F 3-1, Bau-Hung Rd.,
   Shin-Tien Taipei, Taiwan, R.O.C.
   Tel: 886-2-89117712
   Fax: 886-2-29179241
   Contact person: Sophia Lee

2. Date prepared: Sep. 20, 2006

3. Trade name: Merries K-PHATE *Bone graft substitute*

4. Product classification: Class II

5. Device product code and panel code: 87MQV/Orthopedic

6. Common name: Resorbable calcium salt bone void filler device (21 CFR 888.3045)

7. Indications of use:
   Merries K-PHATE is intended to be packed into bony defects of the skeletal system (extremities, spine, or pelvis) which are not intrinsic to the stability of the bony structure. These defects may be surgically created voids or from traumatic injury to the bone. The device gradually resorbs and is replaced with bone during the healing process. Rigid fixation techniques should be used in conjunction with this device.

8. Device description:
   Merries K-PHATE bone graft substitute is a microporous and macroporous biphasic calcium phosphate ceramic consisting of 60% hydroxyapatite and 40% β-tricalcium phosphate. Merries K-PHATE is supplied sterile in various shapes and sizes. The choice of different form or size of the product depends on the type and size of the recipient site. Blocks and wedges are used for large bony defect while granules are used as bone filler for small area.

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9. Statement of substantial equivalence:

Merries K-PHATE *Bone graft substitute* is substantially equivalent in base materials, function and intended use to the following devices:

- MBCP™ (K032268, K043005, and K051774)
  Manufactured by Biomatlante
- Pro Osteon® 500R Resorbable Bone Graft Substitute (K990131)
  Manufactured by Interpore Cross INTL.
- Vitoss® Scaffold Synthetic Cancellous Bone Void Filler (K032409)
  Manufactured by Orthovita, Inc.
- BoneSave™ Bone void Filler(K033258)
  Manufactured by Howmedica Osteonics Corp.

10. Testing summary:

- Chemical requirements conform to the ASTM F1185-88 "Standard specification for composition of ceramic hydroxylapatite for surgical implants" and ASTM F 1088-87 "Standard specification for beta-tricalcium phosphate for surgical implantation".
- After taking into account the intended use and the device contact duration (>30days), the following biocompatibility tests have been completed and results support that Merries K-PHATE is non-cytotoxic, non-sensitizing, non-mutagenic, and compatible with surrounding tissues.

Biocompatibility Tests	Results
Cytotoxicity	Pass
Subcutaneous Irritation Test	Pass
Guinea Pig Skin Sensitization Study (Maximization Test)	Pass
Implantation Test	Pass
Sister Chromatid Exchange Test	Pass

- Merries K-PHATE has been tested of sterilization dose auditing for sterility.

Summaries and reports of all data are contained in the Premarket Notification Submission.

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Shin-Tien Taipei, Taiwan,

11. Summary of technological characteristics:

The device is substantial equivalence to the predicate devices based on the same material characteristics and intended use. In additional, biocompatibility tests and well documented material support its safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Merries International Inc.
% Ms. Sophia Lee
2F 3-1, Bau-Hung Road
Shin-Tien, Taipei
China

MAR 10 2008

Re: K063157
Trade/Device Name: Merries K-PHATE Bone Graft Substitute
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV
Dated: January 15, 2008
Received: January 15, 2008

Dear Ms. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2.3 Statement of indication for use

510(k) Number (if known): K063157

Device Name: Merries K-PHATE *Bone graft substitute*

Indications for Use:

Merries K-PHATE is intended to be packed into bony defects of the skeletal system (extremities, spine, or pelvis) which are not intrinsic to the stability of the bony structure. These defects may be surgically created voids or from traumatic injury to the bone. The device gradually resorbs and is replaced with bone during the healing process. Rigid fixation techniques should be used in conjunction with this device.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

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